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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,387	07/02/2003	Jeffrey E. Stahmann	279.580US1	3196

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EXAMINER	
LEE, YUN HAENG NMN	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,387	STAHMANN ET AL.	
	Examiner	Art Unit	
	Yun H. Lee	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-34,37-50,53 and 54* is/are rejected.

7)☒ Claim(s) *35,36,51,52,55 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 8-34, 38-50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. (US Pat. No. 6,076,015) in view of Street et al. (US Pat. No. 6,589,188).

Regarding claim 1, Hartley et al. discloses an apparatus (100) comprising:

an implantable housing (130), the implantable housing comprising:

a thoracic monitor circuit (col. 6 lines 27-29), inherently including an output to provide time domain thoracic information;

a signal processor circuit (155);

a controller circuit (165), the controller circuit comprising an input coupled to the spectrum analyzer output (160) to receive the pulmonary physiological state classification; and

a therapy circuit (170), coupled to the controller circuit, to deliver therapy to the subject.

Hartley et al. does not disclose the signal processor circuit comprising:

a time-to-frequency domain converter circuit, including an input coupled to the thoracic monitor circuit output to receive the time domain thoracic information, and including an output providing frequency domain thoracic information; and

a spectrum analyzer circuit, including a input coupled to the time-to-frequency domain converter circuit output to receive the frequency domain thoracic information, and including an output to provide a classification of a pulmonary physiological state using a respiration component of the frequency-domain thoracic information.

Street et al. discloses performing spectral analysis on the thoracic monitor circuit output (col. 4 lines 25-26) to identify whether the output signal has a significant frequency component in the range that is shown during periodic or Cheyne-Stokes breathing (col. 7 line 64 – col. 8 line 5). In order to do spectral analysis on the transthoracic impedance information in the time domain, the apparatus must inherently have a time-to-frequency domain converter circuit and a spectrum analyzer circuit. Further, Street et al. discloses providing a classification of a pulmonary physiological state using the frequency-domain thoracic information (col. 6 lines 51-52). The thoracic information is disclosed as a respiration component (col. 6 lines 7-8). Street et al. teaches that periodic breathing data obtained by the spectral analysis may be an indicator of increased mortality risk and that a clinician may take appropriate steps to respond to such indications (col. 8 lines 11-14).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to make the signal processing circuit of Hartley et al. comprising a time-to-frequency domain converter circuit and a spectrum analyzer circuit as disclosed in

Street et al. in order to obtain an indicator of increased mortality risk which a clinician may use to take appropriate steps to respond to such indications.

Hartley et al. also does not disclose controlling the delivery of therapy using the pulmonary physiological state classification. As mentioned above, Street et al. teaches that periodic breathing data obtained by the spectral analysis may be an indicator of increased mortality risk and that a clinician may take appropriate steps to respond to such indications (col. 8 lines 11-14). Thus, it would have been obvious to control the delivery of therapy of Hartley et al. using the pulmonary physiological state classification in order to respond to indications such as increased mortality risk.

Regarding claim 2, Hartley et al. further discloses the apparatus of claim 1, in which the thoracic monitor circuit comprises an impedance detector circuit (col. 6 lines 28-29).

Regarding claim 3, Hartley et al. further discloses the apparatus of claim 2, in which the impedance detector circuit comprises:

a test stimulus circuit (150), configured to be coupled to a subject using implantable electrodes to deliver a test stimulus to the subject; and

a response sensing circuit (155), configured to be coupled to the subject using implantable electrodes to receive a signal correlative to transthoracic impedance in the subject in response to the test stimulus delivered to the subject. (col. 6 lines 16-29)

Regarding claim 4, Hartley et al. does not disclose the thoracic monitor circuit comprising an acceleration detector circuit. Street et al. discloses using an accelerometer to determine activity to avoid introduction of extraneous influences that may be present with patient exercise or other activity (col. 6 lines 32-40). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have the thoracic monitor circuit of Hartley et al. comprise an acceleration detector circuit to determine activity to avoid introduction of extraneous influences that may be present with patient exercise or other activity.

Regarding claim 5, Hartley et al. further discloses the apparatus of claim 1, in which the thoracic monitor circuit comprises an analog-to-digital (A/D) converter circuit (425).

Regarding claim 6, Hartley et al. does not disclose the time-to-frequency domain converter circuit comprising a fast-Fourier transform (FFT) module. In the previous Office Action, Examiner took Official Notice of the fact that it is well known to use FFT modules for converting signals in the time domain to signals in the frequency domain. Since Applicant failed to argue this assertion, this feature is now taken to be admitted prior art. FFT modules are advantageous because of their efficiency in transforming the signal. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have the time-to-frequency domain converter circuit of Hartley et al. comprise a fast-Fourier transform module since it is efficient to use FFT modules for transforming signals in the time domain to signals in the frequency domain.

Regarding claim 8, Hartley et al. further discloses the apparatus of claim 1, further including a telemetry circuit (185), coupled to the output of the spectrum analyzer to receive the pulmonary physiological state classification for communication from the implantable housing.

Regarding claim 9, Hartley et al. does not disclose computing a physiological indicator using a heart rate variability (HRV) component of the frequency-domain thoracic information. In the previous Office Action, Examiner took Official Notice of the fact that it is well known to measure the power spectrum of HRV in order to predict disease independent of other prognostic indicators. Since Applicant failed to argue this assertion, this feature is now taken to be admitted prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to configure the spectrum analyzer of Hartley et al. to compute a physiological indicator using a heart rate variability (HRV) component of the frequency-domain thoracic information.

Regarding claim 10, all the limitations have been met by the above discussion of claim 1, except for the frequency domain adaptive filter. Hartley et al. discloses an adaptive filter (435) which is used to attenuate certain frequency components of the signal (col. 1 3 lines 38-40). Although, in the disclosure of Hartley et al., the adaptive filter receives and processes a time domain input signal, the filtering is processed essentially in the frequency domain. In view of the above discussion of claim 1, it would have been

obvious for the adaptive filter to comprise a first input coupled to the output of the time-to-frequency domain converter circuit and an output coupled to the input of the spectrum analyzer since the filter is coupled to the streamline processing of the thoracic impedance signal. Further, since, in this case, the incoming signal is a frequency domain signal, it would have been obvious to configure the adaptive filter to be a frequency domain adaptive filter.

Regarding claim 11, Hartley et al. further discloses the apparatus of claim 10, further comprising:

a depolarization detector circuit (175); and

a heart rate interval timer circuit, coupled to the depolarization detector circuit, the heart rate interval timer circuit including an output coupled to a second input of the frequency domain adaptive filter (col. 14 lines 2-5).

Regarding claim 12, Hartley et al. further discloses the apparatus of claim 1, in which the signal processor circuit includes a digital signal processor (DSP) circuit (405).

Regarding claim 13, the above discussions of claims 1, 10 and 11 meets all the limitations except for the frequency domain adaptive filter being configured to distinguish a respiration component of the frequency domain thoracic information from a heart contraction component of the frequency domain thoracic information. Hartley et al. discloses the frequency domain adaptive filter (435) being configured to distinguish a

respiration component (ventilation) of the frequency domain thoracic information from a heart contraction component (stroke) of the frequency domain thoracic information (col. 14 lines 30-33).

Regarding claims 14-24, the limitations are met by the above corresponding respective discussions of claim 2-6, 1, 7-9, 11 and 12, respectively.

Regarding claims 25-31, the limitations are clearly met by the above discussions except for the specific classifications as currently amended in claim 25. See discussion of claims 37 and 53.

Regarding claim 32, Street et al. further discloses classifying the pulmonary physiological state as indicative of normal respiration (22).

Regarding claim 33, Street et al. further discloses classifying the pulmonary physiological state as indicative of periodic respiration (36).

Regarding claim 34, Street et al. further discloses classifying the pulmonary physiological state as indicative of Cheyne-Stokes respiration (col. 5 lines 48-49).

Regarding claim 38, the limitations are met by the above discussion of claim 8.

Regarding claim 39, Examiner, in the previous Office Action, took Official Notice of the fact that it is well known to downloaded physiological data from an implantable device to an external device and store the data in a non-implanted memory in the external device such that a clinician or user can later retrieve the data. Since Applicant failed to argue this assertion, this feature is now taken to be admitted prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to store the pulmonary physiological state of Hartley et al. in view of Street et al. for a predetermined time in a non-implantable memory such that a clinician or user can later retrieve the data.

Regarding claim 40, Examiner, in the previous Office Action, took Official Notice of the fact that is it well known to display a trend of stored physiological data. Since Applicant failed to argue this assertion, this feature is now taken to be admitted prior art. This type of display is advantageous since a clinician or user can visualize the progression of a disease or physiological state. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have displayed a trend of stored pulmonary physiological states so that a clinician or user can visualize the progression of a disease or physiological state.

Regarding claim 41, the above discussions of claims 1, 10 and 11 meets all the limitations except for using a cutoff frequency that varies as a function of the detected

heart rate. Hartley et al. discloses using a cutoff frequency that varies as a function of the detected heart rate (col. 13 lines 66-67).

Regarding claims 42-50 and 54, the limitations are clearly met by the above discussions.

3. Claims 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. (US Pat. No. 6,076,015) in view of Street et al. (US Pat. No. 6,589,188) further in view of Zhu et al. (US Pat. Appl. Pub. No. 20030028221). Zhu et al. teaches classifying the pulmonary physiological state as indicative of pulmonary fluid accumulation (112). Zhu et al. further teaches that it is important to detect pulmonary fluid accumulation since it may result in labored breathing and may even result in death. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have provided for classifying the pulmonary physiological state as indicative of pulmonary fluid accumulation in the invention of Hartley et al. in view of Street et al. so that problems such as labored breathing and imminent death can be attended to.

Allowable Subject Matter

4. Claims 35, 36, 51, 52, 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed 5/30/2006 have been fully considered but they are not persuasive. As discussed above regarding claims 1-9 and 12, it would have been obvious to one of ordinary skill in the art to control the delivery of the therapy using the pulmonary physiological state classification. Regarding claims 10-11, 13-24, 41-50 and 54, the purpose of the adaptive filter, in the present application and in the applied reference, is to attenuate certain frequencies. Signal processing in both the time domain and the frequency domain is extremely well known. Depending on the nature of the incoming signal, it would have been obvious to choose the appropriate filter domain: time or frequency. Regarding claims 25-40, the arguments are moot since they depend on the subject matter of claim 37. Regarding claims 37 and 53, these claims do not mention anything about a frequency domain thoracic signal. Although their parent claims do mention this, the corresponding rejections address this issue.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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yhl